

MAY - 4 2000

**510(k) Summary**  
**ORATEC® Electrosurgical Probes**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K 000 691

**Submitter:**

ORATEC® Interventions, Inc.  
3700 Haven Court  
Menlo Park, CA 94025  
Establishment Registration # 2953127

**Contact:**

Jennifer Brennan  
Regulatory Affairs Associate  
Telephone: (650) 369-9904  
Fax: (650) 369-9902

**Date Prepared:** February 25, 2000

**Device Name**

**Classification Name:** Electrosurgical device  
**Common/Usual Name:** Electrosurgical accessory  
**Proprietary Name:** ORATEC® Vulcan™ Electrosurgical Probes:  
Vulcan Ligament Chisel™  
Vulcan Micro Ligament Chisel™  
Vulcan Eflex™ Ligament Chisel™  
Vulcan Ablator™

**Predicate Devices:**

ORATEC Electrosurgical Probes  
Mitek Electrosurgical Probes  
Linvatec Electrosurgical Probes  
ArthroCare Electrosurgical Probes

**Device Description:**

The devices described in this 510(k) are sterile, disposable devices intended for use with the ORATEC Vulcan ElectroThermal Arthroscopy System (EAS) RF Generator.

**Technological Characteristics:**

The ORATEC Vulcan Electrosurgical Probes are technologically the same as the predicate devices. All devices use high frequency electrosurgical current to achieve the intended clinical purpose.

**Conclusion:**

Based on the fundamental scientific technology characteristics, performance, and comparison to the predicate devices, the ORATEC Vulcan Electrosurgical Probes are substantially equivalent to the predicate devices: ORATEC, Mitek, Linvatec, and ArthroCare Electrosurgical Probes under the Federal, Food, Drug and Cosmetic Act. ORATEC Electrosurgical Probes are manufactured and distributed by ORATEC Interventions, Inc.

**Indications for Use:**

The ORATEC Vulcan Electrosurgical Probes, in combination with ORATEC Vulcan ElectroThermal Arthroscopy System (EAS) Generator, is intended for general surgical use, including orthopaedic and arthroscopic applications of resection, ablation, excision of soft tissue, hemostasis of blood vessels and in coagulating soft tissues in joints including but not limited to the knee, shoulder, wrist, hip, etc. Arthroscopic surgery could include, for example, the following:

Examples of Arthroscopic Surgery	All Joints	Joint Specific		
		Knee	Shoulder	Wrist
Debridement	x			
Tendon	x			
Cartilage	x			
Fracture	x			
Plica Removal	x			
Resection	x			
Synovectomy	x			
Bursectomy	x			
Ablation	x			
Excision of Soft Tissue	x			
Scar Tissue	x			
Hemostasis of Blood Vessels	x			
Coagulating Soft Tissues	x			
Ligament	x			
Articular Cartilage	x			
Chondroplasty	x			
Meniscectomy		x		
Meniscal Cystectomy		x		
PCL/ACL Debridement		x		
Notchplasty		x		
Lateral Release		x		
Labral Tear		x		
Acromioplasty			x	
Rotator Cuff Debridement			x	
Subacromial Decompression			x	
CA Ligament Resection			x	
Capsular Release			x	
Triangular Fibrocartilage (TFC)				x



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 4 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Jennifer Brennan  
Regulatory Affairs Associate  
ORATEC Interventions, Inc.  
3700 Haven Court  
Menlo Park, California 94025

Re: K000691  
Trade Name: Vulcan Electrosurgical Probes: Vulcan Ligament Chisels™ (913001, straight; 913002, angled; 913003, curved; 913004, hook  
Vulcan Micro Ligament Chisels™ (913004, angled; 913005, curved; 913004, hook)  
Vulcan E-flex™ Ligament Chisel (913007, angled); and  
Vulcan Ablator™ Probes (910001, 90°; 910002, 30°; 910003, 60°; 910007, 90° High Profile)  
Regulatory Class: II  
Product Code: HRX, GEI  
Dated: February 25, 2000  
Received: February 29, 2000

Dear Ms. Brennan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

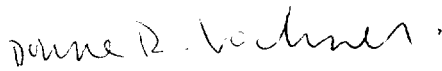
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

# INDICATIONS

Page \_\_\_\_\_ of \_\_\_\_\_ 510(k) Number (if known): K000691

Device Name: ORATEC Vulcan Electrosurgical Probes

## Indications for Use:

The ORATEC Vulcan Electrosurgical Probes, in combination with ORATEC Vulcan ElectroThermal Arthroscopy System (EAS) Generator, is intended for general surgical use, including orthopaedic and arthroscopic applications, for resection, ablation, excision of soft tissue, hemostasis of blood vessels and in coagulating soft tissues in joints including but not limited to the knee, shoulder, wrist, hip, etc. Arthroscopic surgery could include, for example, the following:

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Synovectomy	X			
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Ligament	X			
Articular Cartilage	X			
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Meniscectomy		X		
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PCL/ACL Debridement		X		
Notchplasty		X		
Lateral Release		X		
Labral Tear		X		
Acromioplasty			X	
Rotator Cuff Debridement			X	
Subacromial Decompression			X	
CA Ligament Resection			X	
Capsular Release			X	
Triangular Fibrocartilage (TFC)				X

K000691

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER  
PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dennis R. Vachney.  
(Division Chief-Off)  
Division of General Restorative Devices  
510(k) Number K000691

Prescription Use ✓  
(Per 21 CFR 801.109)

OR Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)